Randomized controlled trial of a self-management intervention in persons with spinal cord injury

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PERSPECTIVES IN REHABILITATION: DEVELOPING ROBUST RESEARCH DESIGNS

Randomized controlled trial of a self-management intervention in persons with spinal cord injury: design of the HABITS (Healthy Active Behavioural IntervenTion in SCI) study

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Purpose: **To evaluate the effectiveness of a 16-week self-management intervention on physical activity level and self-management skills (self-efficacy, proactive coping and problem solving skills) in persons with chronic SCI.** ***Method and design*****: Multicenter randomized controlled trial (RCT). Eighty persons with a SCI for at least 10 years and aged 18 to 65 will randomly be assigned to the intervention (self-management) or the control group (information provision). During the 16-week self-management intervention (one home-visit, five group and five individual sessions) active lifestyle will be stimulated and self-management skills will be taught. Data will be collected at baseline (T0), 16 (T1) and 42 (T2) weeks after baseline. Primary outcome measure is level of daily physical activity (self-report/objectively measured). Secondary outcome measures are self-managements skills, stage of behaviour change and attitude.** ***Conclusion:*** **This is the first RCT on self-management in people with chronic spinal cord injury. This trial will provide knowledge on the effects of a self-management intervention on physical active lifestyle in persons with a long-term SCI.**

Keywords: Coping skills, health promotion, health behaviour, physical activity, problem solving, self-management, self-efficacy, spinal cord injuries

Implications for Rehabilitation

- Persons with long-term SCI benefit from a higher activity level in terms of health- and psychological benefits.
- Self-management interventions have shown to be effective in modifying behaviours and preventing health problems in different chronic disorders.
- This study aims to enhance a physically active lifestyle in persons with long-term SCI by improving self-management skills (self-efficacy, problem solving & proactive coping) through a self-management intervention.

Introduction

In the general population, inactivity is a well-known risk factor for the development of secondary health conditions (SHCs). Physical activity (PA) can counteract these problems and may lead to potential health benefits [1]. Many persons with chronic spinal cord injury (SCI) show a serious inactive lifestyle [2–6]. Due to less opportunities and barriers to be active, the risk of inactivity is higher for this population in comparison to able-bodied persons and persons with other chronic disorders [7], hence extra attention is needed.

An inactive lifestyle in persons with SCI has been associated with de-conditioning and secondary health conditions [8–10], and a higher activity level has found to be associated with several physiological and psychological benefits [8–18]. Therefore, encouraging an active lifestyle is important in this population. Interventions conducted to promote PA in persons with SCI showed moderate benefits [19,20]. Furthermore, none of these interventions were

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evaluated on the long-term. Educational programs to promote PA or to prevent specific secondary health conditions in SCI showed effectiveness on knowledge transfer [21,22]. However, self-management interventions showed that providing only information is insufficient to change behaviour [23–28]. Behavioural interventions are needed to implement health-related goals [23–28] and to facilitate behaviour change [29–31].

Self-management

Self-management is an important factor in the development and treatment of an inactive lifestyle, SHCs and de-conditioning in persons with SCI [18,19]. A suitable definition of self-management is given by Barlow et al. (2001; p.178) [31]; "*Self-management refers to the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition. Efficacious self-management encompasses ability to monitor one's condition and to affect the cognitive, behavioural and emotional responses necessary to maintain a satisfactory quality of life*".

To stimulate effective self-management, education programs should incorporate more behavioural and active learning strategies in addition to knowledge transfer in order to change specific behaviours [23,24,26,32]. Furthermore, persons have to be intrinsically motivated [33,34] and able to perform the suitable action at the right time [31].

Different theories and concepts support the potential benefits of effective self-management, as there are: (i) Self-regulation [35], which is defined as the way in which people control and direct their own actions in order to meet their goals, (ii) Proactive coping, which assumes that people do not only react on threatening situations, but that they can also anticipate on situations that may threat or influence their goals in the future [36,37], (iii) Problem solving, which entails a complex process that includes two broad components: problem orientation and problem-solving skills [21,38], and (iv) Social cognitive theory [39], which is related to self-efficacy, that suggests that confidence in one's ability to perform certain behaviour is strongly related to one's ability to perform that behaviour [39].

Similar self-management interventions have shown to be effective in preventing health problems and in modifying behaviour in different chronic disorders [31,40,41]. However, the effects of such a self-management intervention has to our knowledge, never been evaluated in persons with chronic SCI.

The current **H**ealthy **A**ctive **B**ehavioural **I**nterven**T**ion in **S**CI (HABITS) study aims to evaluate the effects and mechanisms of a structured self-management active lifestyle intervention in persons with SCI. This study is part of the research program "Active LifestyLe Rehabilitation Interventions in aging Spinal Cord injury" (ALLRISC) [18], that has been developed to address problems related to PA, de-conditioning and SHCs in persons who have a SCI for at least 10 years [42]. It is hypothesized that this intervention will show beneficial effects on (i) a more active lifestyle, (ii) self-management skills, such as proactive coping, problem-solving ability and self-efficacy, and (iii) that participants with improvements in self-management skills will show more favourable effects on active healthy lifestyle than participants who do not improve in self-management skills.

Methods and design

Study design

HABITS is a multicentre randomized-controlled trial. The experimental group receives a 16-week self-management intervention targeted at physical active & healthy lifestyle. The control group will only receive information about active lifestyle in SCI, including one information meeting and a booklet on how to stay fit with SCI [43] (see Figure 1). The four participating rehabilitation centres (RC's) are Rijndam (Rotterdam), De Hoogstraat (Utrecht), Adelante (Hoensbroek), and Het Roessingh (Enschede). Measurements take place at the beginning of, directly after and half a year after termination of the intervention (Figure 1).

Ethical approval

Multicentre approval was granted by the Erasmus MC Medical Ethics Committee, The Netherlands, Local approval was granted by all participating centres.

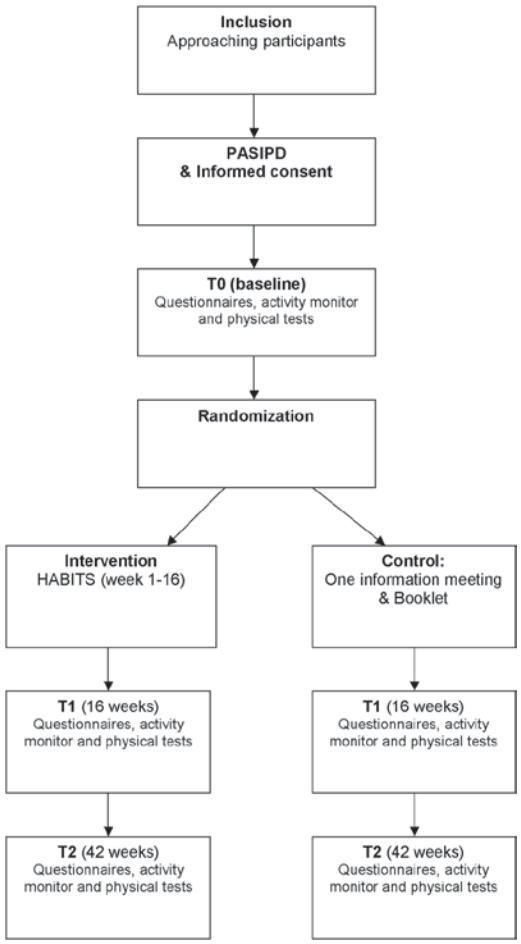

Figure 1. Flowchart study.

Blinding

The randomization within each centre to the intervention or control groups will be done by an independent investigator who will not be involved in the interventions, measurements or the analysis of the data. In each rehabilitation centre (RC) there will be one research assistant that will perform all the tests. This person is not involved in the self-management intervention of the participants and will be blinded for the allocation of groups.

Sample size

The size of the study sample (N = 80) is based on a power analysis with a power of 80%, $\alpha = 0.05$, and an expected increase of 30 min per day in the duration of dynamic activities (wheelchair-driving, general movement; as assessed with the accelerometry-based activity monitor) in the experimental group compared to no change in duration of dynamic activities in the control group. The calculations are based on levels of daily physical activity as found in persons with SCI in previous studies of our department [7,44].

Participants

Inclusion criteria

Adults with a spinal cord injury will be eligible for inclusion if they meet the following criteria:

- Age: 28–65 years.
- Time since injury (TSI): at least 10 years.
- PASIPD score (Physical activity scale for individuals with physical disabilities) lower than the 75th percentile of a Dutch SCI population. The cut-off score is 30 [45].
- The participant should be able to use a hand-rim wheelchair.

Exclusion criteria

Participants will be excluded from the study if they meet any of the following criteria:

- Progressive disease or severe co-morbidities.
- Psychiatric problems that would interfere with the study.
- Insufficient knowledge of the Dutch language to understand the purpose of the study and the testing methods.
- No intention to change exercise behaviour in the next 6 months.

Recruitment

Participants will be recruited from the participating centres. The physician of the department will pre-select former inpatients using information from medical charts. Persons who meet the inclusion criteria regarding age, TSI, and wheelchair mobility will receive the patient information letter. One week later the person is contacted by the research assistant to check the other in- and exclusion-criteria and to provide the opportunity to ask questions. If they are eligible and willing to participate, they will be asked to sign the informed consent form.

Randomization

Directly after the first measurement participants will be randomly allocated to the control or experimental group per RC by means of blocked randomization per centre, with a block size of 6. A statistician will make a randomization scheme.

Intervention

Theoretical framework

This study is based on a theoretical framework (see Figure 3) that serves as scientific background and was used to design the intervention and to select outcome measures. This theoretical framework combines two well-known models: Theory of Planned Behaviour (TPB) [46] and the Transtheoretical Model (TTM) [47]. TPB assumes that intention is required to perform (new) behaviour, and intention is influenced by attitude, subjective norms, and perceived behavioural control [46]. The Transtheoretical Model of Behaviour Change assesses an individual's readiness to act on a new healthier behaviour [47], which also applies to active lifestyle exercise behaviour [48]. The five stages of (exercise) change (SToC) range from precontemplation (no intention to change exercise behaviour) to maintenance (people changed their exercise behaviour and maintained this change for more than 6 months), see Figure 2 [47]. In this framework we define "intention" (TBP) as the first three stages of the TTM and "behaviour" (TBP) the last two stages of TTM. In addition we assume that proactive coping facilitates the step from intention to performing behaviour. Positive effects between proactive coping and behaviour change are found in different studies [40,49–51].

Sessions

The self-management intervention consists of one home visit, five individual and five group sessions, during a total of 16 weeks (see Table I). The content of the intervention is described in Table I.

Home visit

During the home visit the counsellor gets an impression of the participant, and investigates the participants' stage of exercise change [52]. This enables the counsellor to tailor the intervention to the participant [53]. Furthermore the environment (at home and outdoors) will be observed for PA possibilities.

Group sessions

Group sessions will be used as a tool to motivate participants on specific behaviours and to enhance their self-efficacy. Contributing factors include methods from the social cognitive theory [39,41], like peer support and mastery experiences.

The group sessions have different themes (see Table I) associated with self-management, PA and health, but share the same format; feedback, short introduction- and interactive elaboration of the theme and making action/coping plans. The group number will be between 6 and 8. Each session will last about 2.5 h.

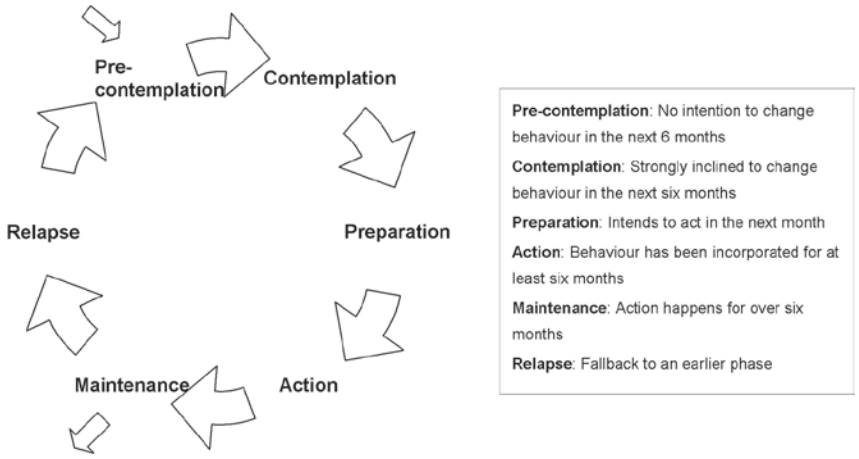

Figure 2. Stages of behaviour change.

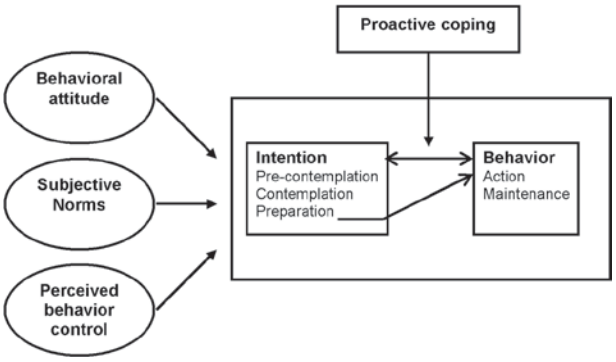

Figure 3. Theoretical framework.

Individual sessions

The individual sessions are used to monitor the participants on their exercise- and health behaviour and to provide extra support by the counsellor. For practical reasons, these sessions will executed by telephone.

Counsellor

The intervention will be provided by a counsellor who has experience in the treatment of persons with SCI (e.g. physiotherapist, occupational therapist or a specialized nurse), and followed training in motivational interviewing (MI). MI is a directive client-centred counselling style to elicit behaviour change by helping clients to explore and resolve their ambivalence towards change [54]. MI has been shown an effective approach to change behaviours and lifestyle [55], and support has been found for the clinical utility of this technique in exercise settings [56].

To be good self-managers, participants have to be self-reliant in finding information, and solutions for problems [40,41]. Therefore, learning how to seek and utilize recourses is also part of the intervention, and it is the task of the counsellor to take up a supporting and facilitating role [41,57].

In addition, the intervention has to be closely tuned to the goals and expectations of the participants in order to motivate them to change their current behaviour [21,41]. This will be accomplished by linking the different sessions to self-chosen goals of the participants.

Table I. Overview HABITS intervention different sessions.

Week	Home visit	Group session	Individual session
1	Start of HABTIS Home visit		
2			
3		1. Introduction: Active lifestyle vs. Health	
4			Telephone session 1
5		2. Sports & leisure PA	
6			Telephone session 2
7		3. Healthy lifestyle & Dealing with emotions	
8			
9			Telephone session 3
10			
11		4. Communication & Social support	
12			
13			Telephone session 4
14		5. Booster session	
15			
16			Telephone session 5

Intervention recourses

Action and coping plans

A stepwise action & coping plan (based on the proactive coping plan of Aspinwall et al. [36] and other effective interventions [36,37,49] concerning PA- and health goals will be made by the participant during the sessions. This plan helps the participant formulate self-chosen, concrete, and achievable goals. Using action plans to promote PA has found to be effective in individuals with SCI [58].

Odometers

Participants will receive feedback on their activity level by using odometers which register the distance travelled with a wheelchair. Odometers are an effective technique for promoting PA [59,60].

Counsellors manual and workbook

The counsellor receives a manual including a detailed description of the content of the different sessions and directives on how different parts of the sessions can be executed.

A self-guided workbook for participants will be used as a reference book for the intervention and will contain small assignments to allow the participants to prepare for the sessions.

Measurements

Primary outcome measures

Objectively measured level of everyday physical activity

To objectively measure the level of daily physical activity (PA), an accelerometer-based device (ActiGraph GT3X+ (AG)) will be used [61]. One AG will be worn on the wrist and one will be attached to a wheel of the wheelchair. In this way, independent wheelchair driving, being pushed and other arm activity can be distinguished.

Participants will wear the AG continuously for 5 consecutive days, except while swimming, bathing or sleeping. To avoid measurement bias, the goal and working principle of the activity monitor will only be explained to the participants after all measurements have been completed. During the measurement they receive the instruction to continue their ordinary daily activities.

The parameters that will be analysed are duration of wheelchair-driving and static activities (e.g. lying and sit still) per day.

Self report daily PA

Self-reported level of PA will be assed by the Physical Activity Scale for Individuals with Physical Disabilities (PASIPD) [62]. The PASIPD consists of 11 items concerning sports, hobbies, household- and work related activities. The questionnaire assesses the number of days a week and the hours a day a certain activity has been performed during the past 7 days. The total score of the PASIPD is created by multiplying the average hours per day for each item by a Metabolic Equivalent value (MET) associated with the intensity if the activity, MET*hour/week. The PASIPD was able to discriminate between persons with paraplegia and with tetraplegia ($p < 0.02$). PASIPD scores further showed significant moderate correlations (0.36–0.51, $p < 0.01$) with measures of social functioning, and significant weak to moderate correlations with fitness parameters (0.25–0.36, $p < 0.05$) [45]. The PASIPD is the best questionnaire for physical activity available in the Dutch language.

Secondary outcome measures

Self-management skills

Self-management skills are measured with two scales: (i) The SCI exercise self-efficacy scale [63], which measures perceived self-efficacy for various types of physical exercise in persons with SCI. This self-report scale includes 10 items; answers can be given on a 4 point Likert scale (1: not at all true up to 4: exactly true). Internal consistency was 0.93. (ii) The Utrecht Proactive Coping Competence scale [64], which assesses an individual's experienced competency with regard to the various skills associated with proactive coping. This self-report scale includes 21 items; answers can be given on a 4 point Likert scale (1: not capable up to 4: very capable). Internal consistency was between 0.83 and 0.95, and test-retest reliability was between 0.45 and 0.82.

Stage of exercise change

The Questionnaire University of Rhode Island continuous measure questionnaire (URICA-E2) [52] assesses the stage of change for regular exercise and is based on the TTM [47] and a previous questionnaire, the URICA [65]. The URICA-E2 measures the six stages of change (Figure 3) related to exercise. The URICA-E2 consists of 24 items with statements concerning the different stages of exercise change. The items are given on a 1–5 scale, from "strongly disagree" to "strongly agree." Internal consistency (tested in a Norwegian study) for this questionnaire was 0.72–0.92 [66].

Attitude

Attitude will be measured using the questionnaire Exercise: Decisional Balance. This questionnaire reflects the individual's relative weighing of the pros and cons of changing exercise behaviour [67]. The questionnaire consists of 10 statements (5 con's, 5 pro's). The importance of each statement to exercise or not to exercise is asked on a 5-point Likert scale ranging from 1 (not at all) to 5 (extremely). Mean internal consistency was 0.8 for the pro subscale, and 0.7 for the cons subscale. Test-retest reliability was 0.84 and 0.74 for the pros and cons, respectively [67].

Other evaluated outcome measures

In addition the following outcome measures will be evaluated for descriptive reasons and for comparison with the other three ALLRISC studies. These outcome measures will not be fully described but only mentioned here.

Secondary health complications (Spinal Cord Injury Secondary Conditions Scale [68] & Questionnaire Health Problems Spinal Cord Injury) [69], Social support (Social Support for Exercise Behaviour Scale) [70], Demographics (gender, age, smoking, drinking, living situation, medication and re-admission to rehabilitation and/or hospital), Functional Independence (Spinal Cord Independence Measure III) [71,72], Mood (Mental Health Inventory-5) [73,74], Fatigue (Fatigue severity scale) [75–77], Participation (The Utrecht Scale for Evaluation of Rehabilitation-Participation) [78], Quality of Life (five items from the World Health Organization quality of life assessment [79,80].

In addition, the following physical measurements will be performed: Lesion characteristics (International spinal cord injury core data set [81] and the neurological classification of spinal injury developed by the American Spinal Injury Association (ASIA-A)) [82], Anthropometry data (height, body mass, waist circumference), Pulmonary function (Forced expiratory Volume in 1 min (L/%predicted)) [83–85] and Aerobic capacity (VO2peak (L/min)/ POpeak (watts)) measured during a wheelchair treadmill test [86,87].

A process evaluation will be conducted with the cases that have been randomized in the intervention group. Both

quantitative and qualitative data on applicability, compliance, satisfaction and barriers to the protocol will be gathered at the end of the intervention.

Statistics

Multilevel regression analysis will be the main statistical technique to test for differences between the intervention and the control group at the three test moments, as well to test for differences within both groups across the three test moments. This technique allows for missing values and can correct for differences between the participating centres. Level of significance will be $p < 0.05$. For all multilevel analyses, MLwiN software [88,89] will be used.

Discussion

Comparison with other studies

This study is unique in implementing a self-management intervention in SCI in which activity and health behaviour are stimulated by improving self-management skills through a behavioural intervention. There are other studies that use self-management- or other active learning strategies to stimulate physical activity, but these strategies are in most studies an addition to a physical training programme [90].

Strengths and limitations

This study utilizes a theoretical framework to develop a self-management intervention, and to explain the results of the evaluation study. Earlier self-management interventions lack such a scientific background [91]. However, it will still be difficult to identify the effective elements of the interventions, because of the multifaceted nature of this intervention.

The HABITS intervention, if proven effective, can be used as a versatile self-management intervention. Enhancing self-management skills is a very general tool for behaviour change. For instance, the target of the intervention, active lifestyle in this study, can easily be changed. The same applies to the target population.

Physical activity is the primary outcome of this study, but it is possible that participants improve in their stages of change, self-management skills, or exercise attitude, but not yet actually perform new PA behaviour yet, and no change is detected on the AG or the PASIPD [46,92,93]. However, changing forward in the SToC or changing attitude and self-management-skills will be also be seen as positive effects of the study. These secondary outcome measures are a prerequisite to change behaviour. If there are any improvements on these outcome measures, behaviour change in terms of level PA is still possible.

Persons who are unwilling to change their exercise behaviour the next 6 months will be excluded from the study. This probably excludes an important group of subjects in which Motivational Interviewing might have a positive effect [56]. However, it is unlikely that those persons would consent to participate in the study.

Finally, it might be considered that it can be easier to establish behaviour change towards PA in the early stages of SCI. However another PA trial from our group [18] is already been executed in this population, testing a slightly different intervention.

This trial will show whether this self-management intervention has a positive effect on changing physical active lifestyle in persons with long-term SCI. Additionally it should determine if self-management skills can be enhanced and whether they affect PA behaviour and health. The results of this trial are expected in 2014.

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